

9480-7

9/9/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Ms. Cristina Griffin
Agent for Professional Disposables International, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962

SEP 09 2014

Mail to: Attn: Cristina Griffin
Delta Analytical Corporation
12510 Prosperity Drive
Suite 160
Silver Spring, MD 20904

Subject: Sani-Wipe
EPA Registration Number 9480-7
Your Notification Dated August 21, 2014
EPA Received Date August 22, 2014

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to reformat, add optional text, optional label claims, and graphics, is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink that reads "Eric Miederhoff".

Eric Miederhoff
Acting Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number NOTIF

Application for Pesticide - Section I

1. Company/Product Number 9480-7
2. EPA Product Manager Eric Miederhoff
3. Proposed Classification
4. Company/Product (Name) Professional Disposables International, Inc. (PDI) / Sani-Wipe
5. Name and Address of Applicant
6. Expedited Review

Section - II

Amendment - Explain below
Resubmission in response to Agency letter dated
Notification - Explain below
Final printed labels in response to Agency letter dated
Me Too Application
Other - explain below

Explanation: Use additional page(s) if necessary.
Notification per PR Notice 98-10 to re-format, add optional text, optional label claims, and graphics.

Section - III

1. Material this Product will be Packaged in:
Child-Resistant Packaging
Unit Packaging
Water Soluble Packaging
2. Type of Container
3. Location of Net Contents Information
4. Size(s) of Retail Container
5. Location of Label Direction
6. Manner In Which Label Is Affixed to Product

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)
Name Cristina Griffin
Title Agent for Professional Disposables International, Inc. (PDI)
Telephone No. 301-680-7971

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
2. Signature Cristina Griffin
3. Title Agent for Professional Disposables International, Inc. (PDI)
4. Typed Name Cristina Griffin
5. Date August 21, 2014
6. Date Application Received (Stamped)

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[FRONT PANEL]

***SANI-WIPE®**

***NO RINSE HARD, NON-POROUS SURFACE SANITIZING WIPE**

[Previously approved Alternate Brand Names:]

- PDI® FC-7® Food Contact Surface Sanitizing Wipes
- PDI® FC-7® No-Rinse Food Contact Surface Sanitizing Wipes
- PDI® FC-7® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- PDI® Food Contact Surface Sanitizing Wipes
- PDI® No-Rinse Food Contact Surface Sanitizing Wipes
- PDI® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- PDI® Thermo-San® Food Contact Surface Sanitizing Wipes
- PDI® Thermo-San® No-Rinse Food Contact Surface Sanitizing Wipes
- PDI® Thermo-San® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- Sani Professional® Brand Sani-Wipe[s]
- Sani Professional® Brand Table Turners™ No-Rinse Sanitizing Wipe[s]
- Sani-Professional® Brand Thermo-San® Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Thermo-San® No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Thermo-San® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes

***ACTIVE INGREDIENTS**

- *n-Alkyl(C₁₂67%, C₁₄25%, C₁₆7%, C₈, C₁₀, C₁₈,1%) Dimethyl Benzyl
- *Ammonium Chloride..... 0.0175%
- *Isopropyl Alcohol..... 5.4800%
- *OTHER INGREDIENTS 94.5025%
- *TOTAL 100.0000%

[Does not include the weight of the [cloth] [towelette] [or] [wipe]]

***KEEP OUT OF REACH OF CHILDREN**

***CAUTION**

*See back [side] panel for additional precautionary statements

*NET CONTENTS [and/or Net Wt.] _____oz (g) [or lbs. (kg)]

* ___# OF CLOTHS [SIZE of each cloth]

*E P.A. Reg. No.9480 - 7

* EPA Est. No.9480-NY-1 [or EPA Est. No. A=9480-NY-1, B=72956-WI-1, C=72956-AR-1

Alpha character will precede batch number on product container]

[Manufactured by [or for]]:

Professional Disposables International, Inc.

Two Nice-Pak Park, Orangeburg, NY 10962-1376

[For information call: [phone number to be inserted]]

[Made in USA] [with domestic and foreign sourced materials]

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[BACK PANEL]

[Use at least one of the use sites indicated in the paragraph below or in the "For Use In" section below:]

[AREAS OF USE IN FOOD SERVICE AND FOOD PREPARATION:]

*This product is recommended for use in retail food establishments [including [restaurants,] [hotels,] [kitchens,] [airplanes,] [food service in healthcare settings,] [delicatessens,] [supermarkets,] [temporary food establishments], [food processing plants,]] and other food service and food preparation settings where the [control of the hazards] or [prevention] of cross contamination between treated surfaces is of primary importance.

[Recommended for use on cleaned hard, non-porous food contact surfaces in kitchens.]

[Not for in-home use]

[Not for retail sale]

[Not for sale in (*insert state(s)*)]

[FOR USE IN:]

[Restaurants]

[Food Processing Plants]

[Hotels]

[Nursing Homes]

[Schools]

[Cafeterias]

[Airplanes]

[Caterers]

[Cruise Ships]

[Fast Food Chains]

[Poultry/Meat Packing Facilities]

[Motels]

[Day Care Settings]

[Nurseries]

[Healthcare Food Service]

[Delicatessens]

[Temporary Food Establishments]

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***DIRECTIONS FOR USE:**

*It is violation of Federal law to use this product in a manner inconsistent with its labeling.
[Product is ready for use, no mixing or measuring required.]

***FOOD CONTACT SURFACES**

*For use on cleaned [*or thoroughly washed*] then rinsed hard non-porous food preparation surfaces. Surfaces may include: [*Use one or more of the following:*] [tables,] [food preparation tables,] [counter tops] [non-wood cutting boards,] [probe portion of meat thermometers,] [probe portion of food thermometers,] [take out counters,] [cafeteria trays,] [bar tops,] [waitress stations,][food carts] [and] [microwaves,] [ranges,] [reach- in refrigeration and freezer units,] [scales,] [walk-in refrigeration and freezer units,] [work tables,][self service condiment areas,][self service serviceware areas] [*The following uses must be preceded by the words:*" [outside surface[s] of]" *or* "[exterior surface[s] of]":] [beverage dispensers,] [food mixers,] [ice machines,] [steam tables,][griddles,] [chargrills,] [broilers,] [cooking surfaces and [backsplashes,] [ovens,] [pulpers,] [*Add the following after the list of surfaces:*] and other similar hard, non-porous food contact surfaces except for those excluded by this label.*

*Cleaning and Sanitizing Procedure: Thoroughly clean all food contact using suitable detergents, brushes, sponges and any other necessary equipment. Then rinse with potable water and sanitize with Sani-Wipe [*or this product or insert private label product name*]. To sanitize, wipe enough for treated area to remain visibly wet for a minimum of 60 seconds. Let air dry. No rinsing required.

*All applicable health inspection agency code requirements must be followed for cleaning, rinsing and sanitizing.

*+Do not use to sanitize glassware, cookware; eating utensils, and wood cutting boards. Do not use to sanitize food preparation surfaces that are scored or gouged with narrow crevices that cannot be penetrated by wiping. Do not use to sanitize other food contact surfaces which, by their design or configuration, cannot be fully reached or covered by a wet wipe.

[99.999% effective in 60 seconds against Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC #11229) and Shigella boydii (ATCC #9207) on cleaned, hard, non-porous food contact surfaces]

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*Dispensing: [Choose the dispensing directions from below that correspond to the product package.]

[On canister]

To start feed: Remove lid and discard inner seal from canister. Find center of wipe roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep center cap of lid closed to prevent moisture loss.

[On Flexible Pack or Mobile Pack or Belt Pack]

Peel back label slowly. Pull out wipes as needed and reseal label. Unfold wipe.

[On Packet]

Tear open packet. Unfold wipe.

***PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

***CAUTION:** Avoid contact with eyes.

***Do not use for cleansing or sanitizing human skin.**

***FIRST AID**

***If in eyes:** Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

***STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

[For canisters:]

Storage: Do not use or store near heat or open flame. Use product *only* from original container. **Wipe**

Disposal: Do not reuse wipe. Dispose of used wipe in trash. Do not flush in toilet. **Dispenser**

Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse and offer for recycling. If recycling is not available, put in trash collection.

[For flexible packs, mobile packs, belt packs or single packets:]

Storage: Do not use or store near heat or open flame. Use product *only* from original container. **Wipe**

Disposal: Do not reuse wipe. Dispose of used wipe in trash. Do not flush in toilet. **Dispenser**

Disposal: Put empty [flexible pack] or [mobile pack] or [belt pack] or [packaging] in trash collection.

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[Optional non-food contact section. If non-food contact use is on label, all required elements in this non-food contact section must appear on product label under directions for use, after food contact surface items. The asterisks specify passages required if the optional section is used.]

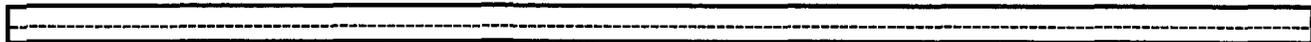
***[NON-FOOD CONTACT SURFACES]**

[Thoroughly preclean if surface is visibly soiled.]

*[Cleaning and] Sanitizing Procedure: For heavily soiled items, clean prior to sanitizing. Use wipe to sanitize surface. Wipe enough for treated surfaces to remain visibly wet for 5 minutes. Use additional wipes as needed to keep entire surface area wet for a full 5 minutes. Let air dry. No rinsing required.

*[Use one or more of the following: [Dining tables,] [chairs,][display cabinets], [employee areas], [garbage cans,][infant high chairs,] [booster seats,] [floors,] [sinks,] [drain boards], [faucets], [toilet seats and rims,] [vanities,] [towel dispensers,] [railings,] [infant-changing tables,] [stall doors,] [bath tubs,] [showers,] [hampers,] [tiled walls,] [telephones,] [shopping carts], [cash registers,] [[store] check-out areas], [playpens,] [cribs], [diaper pails] [and] [doorknobs.]

99.9% effective in 5 minutes against Staphylococcus aureus (ATCC #6538) Salmonella enterica (ATCC #10708), and Klebsiella pneumoniae (ATCC #4352) [in the presence of organic soil (5% blood serum)].



[All below are optional label (placement optional) literature and promotional statements]

Aids in the reduction of cross contamination between treated surfaces.

Antibacterial

Antimicrobial

Cleans, deodorizes and kills common household bacteria

Cost efficient, Less Waste

Cost Savings: Our [product name] wipe is [X] times larger and [X]% less expensive than [PDI's or our [previous]] individually packed wipes. The easy grip canister contains [X] more wipes and creates less waste than individual packets. Now you can do more with less waste!

Eliminates odors

For use on cleaned [and rinsed] hard, non-porous food contact surfaces

For use on hard non-porous surfaces in kitchens [and restrooms].

Its [or Product name's] quat-based formula is [EPA] registered and proven effective against foodborne pathogens listed below* *99.999% effective in 60 seconds against Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC #11229) and Shigella boydii (ATCC #9207) on hard, non-porous food contact surfaces.

Kills 99.999% of Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC #11229) and Shigella boydii (ATCC #9207)] in 60 seconds on cleaned [and rinsed] hard, non-porous food contact surfaces.

Kills common household bacteria

Kills common household bacteria including Staphylococcus aureus (Staph) ,

Kitchen surface wipes

Leaves no harsh chemical residue

Less waste than individually wrapped wipes

No mixing or measuring required

No More Messy Solution Jars

One-step no rinse sanitizer for hard, non-porous non-food contact surfaces.

Premeasured, premoistened sanitizing wipes for use on cleaned hard, non-porous food contact surfaces.

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[Product name] are a convenient method for sanitizing thermometers and other small wares
[Product name] can be part of your facilities' [Hazard Analysis Critical Control Point] [HACCP] plan.
[Product name], food contact sanitizing wipe formulated and designed to sanitize and clean
[insert food contact surfaces].

Recommended for use on hard, non-porous non-food contact surfaces as a one step sanitizer.

Sanitizes hard non-porous surfaces

Simply pull, wipe, and toss to help reduce the risk of cross-contamination[!]

^Always follow directions for use on this [or the] label.

The [Product name] formula is non-corrosive. [Compatible with] [May be used on] [Will not damage]:
[Stainless steel] [Small] [commercial kitchen wares]

The [X wipe size] of [product name] is large enough to use effectively on a variety of small wares and
equipment of busy commercial kitchens. The [new] easy grip canister contains [count] wipes and
creates less waste than individual packets. [product name]: Now you can do more with less waste!

The bacteria are killed in 60 seconds by contact with the liquid in the wipe. The product is effective when
the surface is completely contacted with the wipe.

The fast, easy and effective way to sanitize cleaned, hard non-porous surfaces.

Use to sanitize the probe portion of food and meat thermometers.

Use to sanitize the probe portion of food thermometers.

Use to sanitize the probe portion of meat thermometers.

Versatile: The [wipe size] [Product name] size is ideal for use on thermometers, meat probes, steam
wands, and small ware equipment.

[FOOD CONTACT SURFACES]

*99.999% effective in 60 seconds against Staphylococcus aureus (ATCC #6538), Escherichia coli
(ATCC #11229) and Shigella boydii (ATCC #9207) on hard, non-porous food contact surfaces.

Designed for sanitizing cleaned hard, non-porous food contact surfaces where the control of cross
contamination between treated surfaces is of primary importance

For use in retail and institutional food establishments, food processing plants and other health
department regulated food facilities.

Premeasured, premoistened sanitizing wipes for use on hard non-porous surfaces.

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OPTIONAL GRAPHICS

[The following graphics and statements are optional. They may be placed anywhere on label/container.]



[This graphic shows use of the wipe dispenser.]

NOT A BABY WIPE

NOT FOR USE ON SKIN

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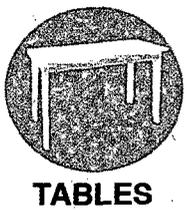
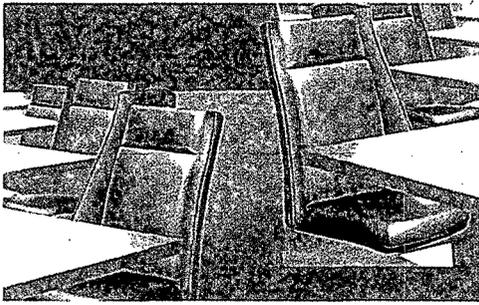
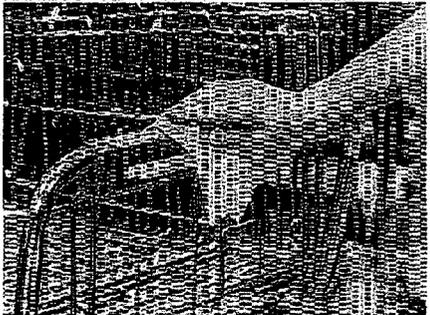
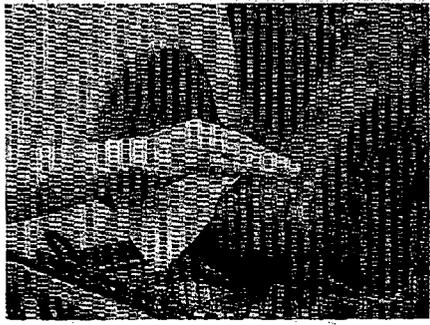
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TABLES



SHOPPING CARTS

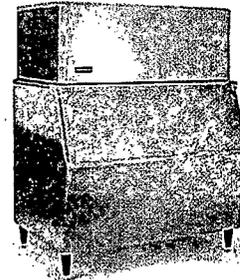
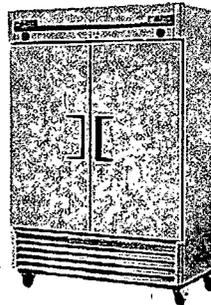
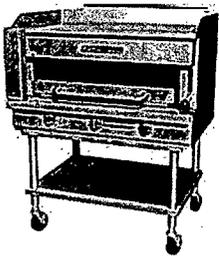
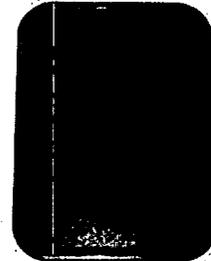
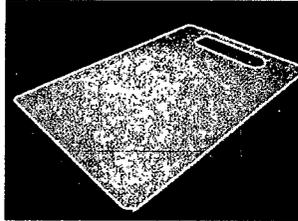
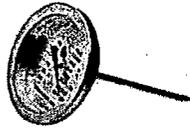
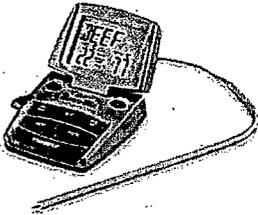
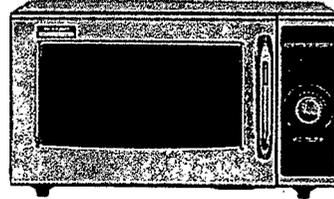
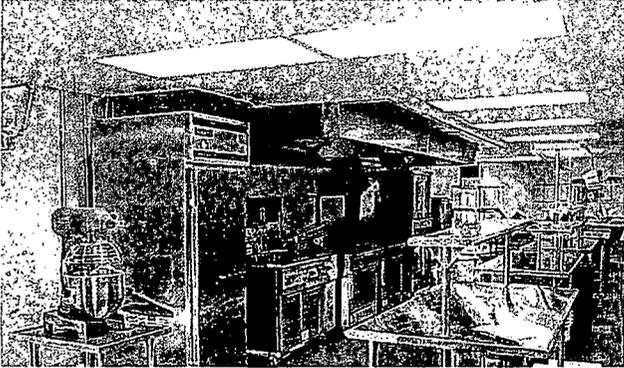
[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



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THERMO-SAN™

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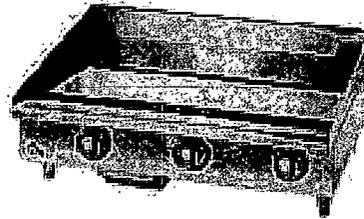
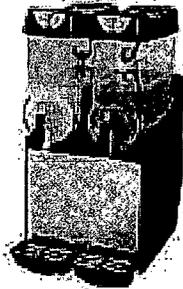
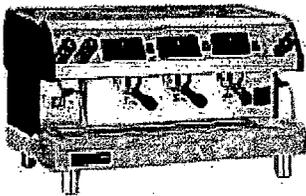
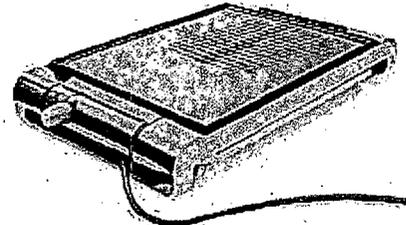
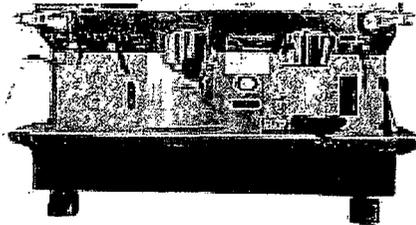
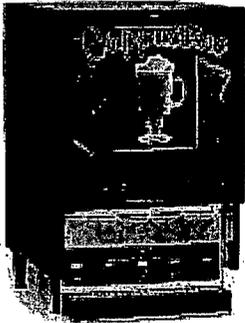
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The terms "Wipe(s)", "Towel(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment. Lists of uses and use sites can be used partially or in their entirety. Any individual statement, claim, restriction or other wording must be used in its entirety, and can not be expanded or shortened by combination, partial deletion, merging, or similar.

[The following graphics and statements are optional.
They may be placed anywhere on label/container.]



THE INFORMATION IN BOX IS NOT PART OF THE LABELING

* - Precedes required label elements, (the symbol "***" is not required to appear on production labels)

[] - Statements in brackets are optional or instructional. Italicized words in brackets are not included

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.

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